REMARKS

Claims 1-21, 23-29, and 30-35 are pending at the time of this action. Reconsideration and allowance of the above-referenced application are respectfully requested. Applicants thank Examiner Bachman for the courtesy extended during the interview on January 24, 2008 with Applicants' attorney, Fred C. Hernandez. The following includes a discussion of the topics discussed in the interview regarding the rejections under 35 U.S.C. §§ 102 and 103.

Previous Rejection Under 35 U.S.C. 112

In the previous office action (mailed May 22, 2007), the examiner rejected claim 1 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The examiner did not repeat the rejection under 35 U.S.C. 112 in the current office action (mailed October 29, 2007.) Accordingly, applicants consider the previous rejection under 35 U.S.C. 112 to be withdrawn.

Rejections under 35 U.S.C. §102

Claims 11-16, 18, 20, 21, 24, 26, 27, 30, 32, and 33 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by US Patent Number 6,269,819 to Oz. However, Oz fails to disclose or suggest every element of the claims.

Claim 11

Claim 11 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;

implanting the annuloplasty device from the catheter directly on an annulus of the heart valve to modify the annulus of the heart valve and reduce regurgitation in the heart valve;

in combination with implanting an annuloplasty device from the catheter directly on the heart valve, deploying a structure that directly attaches to a first valve leaflet and a second valve leaflet of the heart valve so as to reduce regurgitation in the heart valve.

Oz fails to disclose implanting an annuloplasty device from the catheter directly on an annulus of the heart valve. In fact, Oz explicitly teaches away from the above-recited feature of Claim 1. Notably, Oz teaches:

> Nevertheless, recent studies performed by the inventors (Umana et al., Surg Forum 1997) have revealed that posterior ring annuloplasty causes changes in ventricular geometry that lead to paradoxical movement of the normal papillary muscles, further deteriorating ventricular performance. In contrast, the "bow-tie" repair in which the anterior and posterior leaflets of the mitral valve are fixed in opposition appears to enhance annular contractility while preserving ventricular architecture. This has resulted in improved postoperative ventricular function almost uniformly.

Oz, column 2, lines 4-14.

Instead, Oz discloses using a structure such as a grasper to hold the valve leaflets together. The grasper is positioned to contact the leaflets, not the annulus of the heart valve. Oz makes no mention of implanting the annuloplasty device from the catheter directly on an annulus of the heart valve nor does Oz have any suggestion or motivation for implanting an annuloplasty device directly on the annulus of the heart valve.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11. Claims 12-16, 18, and 20 all depend from claim 11 and are patentable over the prior art for at least those reasons articulated with respect to claim 11. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Oz.

Claim 21

Claim 21 recites a method of modifying a heart valve of a patient, comprising:

> advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;
>
> implanting the annuloplasty device from the catheter directly on an annulus of the heart valve to effect a geometric change in an annulus of the heart valve so as to reduce regurgitation in the heart valve; and

in combination with effecting a geometric change in an annulus of the heart valve, coapting leaflets of the heart valve by attaching a structure directly to the leaflets so as to reduce regurgitation in the heart valve.

Oz fails to disclose implanting an annuloplasty device from the catheter directly on an annulus of the heart valve. As discussed above, Oz fails to disclose or suggest any device that is implanted directly on the annulus of a heart valve. Moreover, Oz explicitly teaches away from such a feature.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 21. Claims 24, 26, 27, 32, and 33 all depend from claim 21 and are patentable over the prior art for at least those reasons articulated with respect to claim 21. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Oz.

Claim 27

Claim 27 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;

implanting the annuloplasty device on an annulus of the heart valve so that the annuloplasty device is positioned on an atrial side of the annulus of the heart valve to modify the annulus of the heart valve and reduce regurgitation in the heart valve;

in combination with implanting an annuloplasty device at the heart valve, holding leaflets of the heart valve together at one or more adjacent locations in a manner that reduces regurgitation in the valve.

Oz fails to disclose implanting the annuloplasty device on the heart valve so that the annuloplasty device is positioned on an atrial side of the annulus of the heart valve. As discussed above, Oz fails to disclose or suggest any device that is implanted on the annulus of a heart valve. Moreover, Oz fails to disclose or suggest any device that is positioned on an atrial side of the annulus of the heart valve.

The examiner asserted that Oz discloses that a structure can be deployed on an atrial side of the annulus. However, the examiner failed to cite any section of Oz that discloses a structure positioned on an atrial side of the annulus. The examiner cited Oz at column 7, lines 51-58, in asserting that Oz discloses a structure deployed on an atrial side of the annulus. However, the cited section of Oz makes no mention whatsoever of deploying a structure such that the structure mounts onto an atrial side of the annulus. The cited section of Oz describes a technique wherein the grasper enters the atrium via an atrial stab incision, crosses the valve into the ventricle, then reverts back toward the valve while in the ventricle. A suturing device is then applied to the leaflets "just as in the transventricular approach", which means that the suturing device attaches to the leaflets in the ventricle, not in the atrium. Applicants respectfully request that the examiner explain how Oz discloses or suggests deploying a structure such that the structure can be deployed onto an atrial side of the annulus.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 27. Claims 28, 29, and 31 all depend from claim 27 and are patentable over the prior art for at least those reasons articulated with respect to claim 27. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Oz.

Rejections Under 35 U.S.C. §103

The examiner rejected claims 1-9, 11, 17, 19, 21, 23, 25, 27-29, and 31 under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,056,854 to Boretos in view of U.S. Patent No. 5,061,277 to Carpentier. However, Boretos and Carpentier, both alone and in combination, fail to disclose each and every element of the claims.

Claim 1

Claim 1 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having a first structure releasably coupled thereto;

deploying the first structure from the catheter directly on an annulus of the heart valve, the first structure adapted to modify the annulus so as to reduce regurgitation in the heart valve; and

in combination with deploying the first structure from the catheter directly on the annulus of the heart valve, deploying a second structure directly on the leaflets, wherein the second structure holds leaflets of the heart valve together so as to reduce regurgitation in the heart valve.

Boretos and Carpentier, both alone and in combination, fail to disclose "in combination with deploying the first structure from the catheter directly on the annulus of the heart valve, deploying a second structure directly on the leaflets, wherein the second structure holds leaflets of the heart valve together so as to reduce regurgitation in the heart valve." Boretos discloses an artificial valve that is placeable in a blood vessel. Boretos fails to disclose or suggest deploying a first structure from a catheter directly on the annulus of the heart valve. Moreover, the examiner acknowledged that Boretos fails to disclose deploying a second structure directly on the leaflets. Thus, Boretos fails to disclose each and every element of claim 1.

Carpentier fails to provide the missing teaching. Carpentier discloses a first structure consisting of a ring-shaped valve support that is implanted on the annulus. However, Carpentier fails to disclose a second structure that is deployed directly on the leaflets. The examiner asserted that Carpentier teaches securing the ring to the annulus with sutures 45. However, Carpentier fails to disclose or suggest that the sutures are deployed directly on the leaflets. To the contrary, Carpentier discloses that the sutures extend "generally along the annulus." (Carpentier, col. 4, line 35.) Nowhere does Carpentier disclose a first or a second structure that is deployed directly on the leaflets.

Thus, Boretos and Carpentier, both alone and in combination, fail to disclose or suggest each and every element of claim 1. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1. Claims 2-9 all depend from claim 1 and are patentable over the prior art for at least those reasons articulated with respect to claim 1. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by the cited art. Claim 10, which was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Boretos in view of Carpentier and further in view of Oz, is also patentable based on its own merit as well as based on its dependency on claim 1.

Claim 11

Claim 11 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;

implanting the annuloplasty device from the catheter directly on an annulus of the heart valve to modify the annulus of the heart valve and reduce regurgitation in the heart valve;

in combination with implanting an annuloplasty device from the catheter directly on the heart valve, deploying a structure that directly attaches to a first valve leaflet and a second valve leaflet of the heart valve so as to reduce regurgitation in the heart valve.

Boretos and Carpentier, both alone and in combination, fail to disclose "in combination with implanting an annuloplasty device from the catheter directly on the heart valve, deploying a structure that directly attaches to a first valve leaflet and a second valve leaflet of the heart valve...." The Boretos and Carpentier references are discussed in detail above with reference to Claim 1.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11. Claims 17 and 19 both depend from claim 11 and are patentable over the prior art for at least those reasons articulated with respect to claim 11. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by the cited art.

Claim 21

Claim 21 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;

implanting the annuloplasty device from the catheter directly on an annulus of the heart valve to effect a geometric change in an annulus of the heart valve so as to reduce regurgitation in the heart valve; and

in combination with effecting a geometric change in an annulus of the heart valve, coapting leaflets of the heart valve by attaching a structure directly to the leaflets so as to reduce regurgitation in the heart valve.

Boretos and Carpentier, both alone and in combination, fail to disclose "in combination with effecting a geometric change in an annulus of the heart valve, coapting leaflets of the heart valve by attaching a structure directly to the leaflets... ." The Boretos and Carpentier references are discussed in detail above with reference to Claim 1.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 21. Claims 23, 25, 27-29, and 31 all depend from claim 21 and are patentable over the prior art for at least those reasons articulated with respect to claim 21. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by the cited art.

Claim 27

Claim 27 recites a method of modifying a heart valve of a patient, comprising:

advancing a catheter through the patient's vasculature into the heart from a vascular access point remote from the heart, the catheter having an annuloplasty device releasably coupled thereto;

implanting the annuloplasty device on an annulus of the heart valve so that the annuloplasty device is positioned on an atrial side of the annulus of the heart valve to modify the annulus of the heart valve and reduce regurgitation in the heart valve;

in combination with implanting an annuloplasty device at the heart valve, holding leaflets of the heart valve together at one or more adjacent locations in a manner that reduces regurgitation in the valve.

Boretos and Carpentier, both alone and in combination, fail to disclose implanting the annuloplasty device on an annulus of the heart valve so that the annuloplasty device is positioned on an atrial side of the annulus of the heart valve. Neither reference makes any mention of deploying an annuloplasty device on an annulus of the heart valve so that the annuloplasty device is positioned on an atrial side of the annulus of the heart valve. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 27.

Claims 28, 29, and 31 all depend from claim 27 and are patentable over the prior art for at least those reasons articulated with respect to claim 27. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by the cited art.

CONCLUSION

The above is believed to be a complete response. In view of the amendments and remarks herein, Applicants believe that all claims are now in condition for allowance and ask that these pending claims be allowed. The foregoing comments made with respect to the positions taken by the Examiner are not to be construed as acquiescence with other positions of the Examiner that have not been explicitly contested. Accordingly, the arguments for patentability of a claim should not be construed as implying that there are not other valid reasons for patentability of that claim or other claims. The Examiner is invited to telephone the undersigned to resolve any remaining issues and/or informalities and expedite prosecution of this case.

No fee is believed to be due, however, the Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 37531-501C02US.

Respectfully submitted,

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